HFI-35 7/12/99 ltr

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

M2764n

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-99-75

July 7, 1999

Lawrence Miller, President
Scarborough Fare Fine International Foods Inc.
2650 N. University Dr.
Sunrise, Florida 33322
CFN: 1063837

Dear Mr. Miller:

On January 11, 1999, the Food and Drug Administration (FDA) conducted an inspection of your fish importing facility, located at 2650 N. University Dr., Sunrise, Florida 33322. The investigator, Carlos W. Hernandez, documented a serious deviation from the seafood importing regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). The violation caused the canned kipper (herring) in oil being imported and stored by your firm to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because:

> Failure to implement any of the affirmative steps listed in 21 CFR 123(a)(2)(ii) A-F to ensure that the products you import were processed in compliance with the seafood HACCP regulations.
>
> Failure to have and implement written product specifications, which list all of the appropriate food safety hazards. [21 CFR 123.12(a)(2)(i)]

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination until your firm is fully in compliance with the Seafood HACCP regulations.

Please notify this office, in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct this violation, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Paul R. Bagdikian, Compliance Officer, Food and Drug Administration, 6601 Northwest 25th Street (P.O. Box 59-2256) Miami, Florida 33159-2256.

Sincerely,

Douglas D. Tolen
Director, Florida District